EXHIBIT 9

Safety Evaluation of 1,3-Dimethylamylamine (DMAA) in Dietary Supplement Products

Prepared for:

USPlabs LLC
Dallas, Texas

Prepared by:
Joseph V. Rodricks, Ph.D., DABT
Duncan Turnbull, Ph.D., DABT
Michael Lumpkin, Ph.D., DABT

ENVIRON International Corporation
Arlington, Virginia

Date:
May, 2012

FINAL REPORT

Introduction

ENVIRON International Corporation (ENVIRON) was asked to provide a safety assessment of 1,3-Dimethylamylamine (DMAA) as a dietary ingredient in the dietary supplements sold as Jack3d™ and OxyElite Pro™. ENVIRON has reviewed all of the available data relevant to the assessment of human health and safety and offers the following analysis and opinions.

In developing the safety assessment, ENVIRON reviewed and considered the following data, including data provided by USPlabs:

- A literature search performed by ENVIRON of the PubMed database and ToxNet search engine for published studies of DMAA (and chemical nomenclature synonyms), Jack3d, or OxyElite Pro,
- Six publications of human clinical studies of DMAA, Jack3d™ and/or OxyElite Pro™ in healthy men and women (Bloomer et al. 20011a, 2011b; Whitehead et al. 2012; McCarthy et al. 2012a, 2012b; Farney et al. 2012)
- Four studies in animals and humans published from 1927-1953 which inform on the pharmacological action of DMAA
- The U.S. patent for aminoalkanes (U.S. Patent Office 1944)
- A safety assessment of Jack3d™ performed by CANTOX Health Science International (CANTOX 2011a)
- A safety assessment of OxyElite Pro™ performed by CANTOX Health Science International (CANTOX 2011b),
- USFDA Adverse Event Reporting (AER) listing for dietary supplements (USFDA 2011).

The ToxNet search engine, maintained by the U.S. National Library of Medicine, is linked to the following databases: ChemIDplus, HSDB, Toxline, CCRIS, DART, GENETOX, IRIS, ITER, lact-Med, TRI, Multi-database, Hazmap, Household products, and TOXMAP.

Product Label Usage Direction and Warnings

The labels of both Jack3d™ and OxyElite Pro™ specify that use of these products should be limited to healthy adults, in consultation with a physician. The respective product labels also specify that Jack3d™ should be used no more than 5 days during any 7-day period, while OxyElite Pro™ should be used continuously for no more than 8 weeks, followed by a 4 week cessation of dosing. Both product labels state that no other source of caffeine should be used, nor should Jack3d™ or OxyElite Pro™ be combined with alcohol.

Jack3d™ is sold as a drink mix containing a proprietary blend of arginine α-ketoglutarate, β-alanine, creatine monohydrate, Schisandra chinensis extract, DMAA, caffeine, and excipient

fillers, flavorings, and colorants commonly found in foods. Per the label directions, 1 to 3 scoops (approximately 5.5 to 16.5 g) of Jack3d™ should be mixed with 4 to 8 fluid ounces (120 to 240 mL) of water and consumed approximately 45 minutes prior to physical exercise. Each scoop serving of 5.5 grams of Jack3d™ contains 20 mg DMAA and 125 mg of caffeine. Thus, the label-directed use of Jack3d™ on a daily basis would result in an exposure of 0.3 to 0.9 mg DMAA/kg/day and 1.8 to 5.4 mg caffeine/kg/day for a 70 kg individual.

OxyElite Pro™ is sold in capsules containing a proprietary blend of extracts of *Bauhinia purpurea L., Bacopa monnieri, Cirsium oligiphyllum*, and Yohimbe bark, as wells as caffeine, DMAA, and excipient fillers and colorants commonly found in other foods. Per the label directions, up to 3 capsules/day (2 capsules in the morning, followed by 1 capsule 8 hours later) may be taken. Each capsule contains 20 mg DMAA and 100 mg caffeine. Thus, the label-directed use of OxyElite Pro™ on a daily basis would result in an exposure of 0.3 to 0.9 mg DMAA/kg/day and 1.4 to 4.3 mg caffeine/kg/day for a 70 kg individual.

Characterization, Pharmacology, and Animal Toxicity of DMAA

DMAA is an aliphatic amine that, like other compounds in its class, acts in mammals as a sympathomimetic. That is, DMAA can mimic the effect, but not the intensity, of endogenously produced neuro-active catecholamines, such as epinephrine and norepinephrine (Figure 1), on the sympathetic nervous system. Effects include vasoconstriction, increase in blood pressure and heart rate, and bronchodilation.

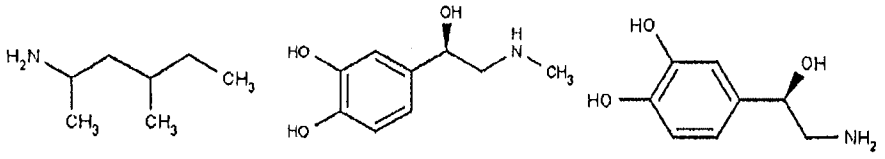

Figure 1. Chemical structures (left to right) of DMAA, epinephrine, and norepinephrine

Although there has existed some debate whether DMAA is a naturally occurring substance (Lisi et al. 2011), it has been definitively detected and quantified in extracts of the geranium plant, *Pelargonium graveloens* grown in the Guizhou Province of China (Ping et al. 1992; Li et al. 2012). The chemical structure, biological interactions, and pharmacological effects of naturally- or synthetically-derived DMAA are identical, making origin of DMAA irrelevant to the assessment of safety.

The ingredients in Jack3d™ and OxyElite Pro™ other than DMAA and caffeine are comprised of amino acid forms, various plant extracts, and creatine. Cantox (2011a, 2011b) reviewed the available laboratory animal data for the effects of these compounds, none of which are expected to contribute to responses of the sympathetic nervous system. This was confirmed in the clinical studies described below, as hemodynamic effects (heart rate and blood pressure), or lack thereof, were similar across the studies regardless of whether subjects ingested DMAA, caffeine, DMAA + caffeine, Jack3d™, or OxyElite Pro™.

DMAA was patented by Eli Lilly and Company in 1944 as a nasal decongestant and approved by U.S. FDA in1948. It was discontinued in 1978, and the NDA (6444) was withdrawn by Eli Lilly in 1983. It was sold as an over-the-counter (OTC) medication because of its ability – similar to ephedrine and amphetamine – to induce vasoconstriction in and reduce swelling of nasal tissues, but without the potent central nervous system stimulation induced by those two compounds (U.S. Patent Office, 1944). From 1948-1978, DMAA was marketed as Forthane® and provided in a nasal inhaler (the M-52 inhaler), which contained 250 mg DMAA. DMAA was reported to induce vasopressor activity of about 1/200th, 1/7th, and 1/225th that of epinephrine in cats, rats, and dogs, respectively (Rohrman and Shonle 1927; Swanson and Chen 1946; Miya and Edwards 1953). Lethal doses in 50% of test animals (LD_{50}) are 185 mg/kg ip in mice and 39-73 mg/kg iv in mice and rats, respectively (Swanson and Chen 1946; Marsh et al, 1951). However, there are no data for lethality following oral exposures, which would be expected to exceed lethal doses given by intravenous or intraperitoneal injection.

Pharmacological Similarities Between DMAA and Caffeine

DMAA and caffeine have similar effects on hemodynamic properties (i.e., heart rate and blood pressure), but differ in effective dose. Single 250 mg caffeine doses (the approximate caffeine dose in 2-3 cups of coffee) or 50 mg DMAA doses in healthy adults resulted statistically similar transient increases in systolic (6-16 mm Hg) and diastolic (6-9 mm Hg) blood pressure (Bloomer et al 2011a; Robertson et al. 1978; Nurminen et al. 1999). These blood pressure changes are offset by reduced heart rate (4-5 bpm) to maintain consistent cardiovascular load (Bloomer et al. 2011b).

Available Human Clinical Data Relevant to Safety Assessment

Six human clinical studies reporting health effects from DMAA and caffeine, Jack3d™, and OxyElite Pro™ use have been performed by researchers at the University of Memphis, published in the peer-reviewed scientific literature, and are summarized below as well as in Table 1. These studies report exposure durations ranging from single doses to 2, 8, and 10 weeks. The effects reported in these studies published in the last two years comport with effects reported for in the older literature, where oral ingestion of 3 mg/kg DMAA in adult male volunteers (over 3-fold

higher than the maximum labeled dose for Jack3d™ or OxyElite Pro™) resulted in a transient increase in systolic blood pressure beginning at about 30 minutes and decreasing after 100 minutes (Marsh et al. 1951).

Bloomer et al. (2011a) investigated the addition of DMAA and caffeine on resting hemodynamic properties and endogenous sympathetic catecholamine (epinephrine and norepinephrine) levels of volunteers for up to 2 hours after dosing. Five male and five female healthy adults consumed a single dosing of 250 mg caffeine (C) (2.8-3.4 mg caffeine/kg), 50 mg DMAA (D50) (0.6-0.7 mg DMAA/kg), 75 mg DMAA (D75) (0.9-1.0 mg DMAA/kg), or combinations of 250 mg caffeine plus 50 (C+D50) or 75 (C+D75) mg DMAA. Heart rate, diastolic blood pressure, and plasma levels of epinephrine or norepinephrine were not significantly different across all treatment groups or from pre-ingestion (control) values. After 60 minutes, systolic blood pressure was increased in all treated groups (122-143 mm Hg in a dose-related manner) above pre-ingestion values (117-121 mm Hg), with D75 and C+D75 producing higher values (132 and 141 mm hg, respectively) than C alone (122 mm Hg) at 90-120 minutes. Likewise, diastolic pressure in all treated groups (76-83 mm Hg) was higher than pre-ingestion values (68-71 mm Hg) after 60 minutes, but combining DMAA with caffeine resulted in values similar to caffeine alone. The rate pressure product (heart rate × systolic blood pressure) increased with DMAA dose. Epinephrine and norepinephrine levels in plasma did not increase in treated groups, suggesting that the reported changes in blood pressure by caffeine and/or DMAA are not mediated by induction of catecholamines, but possibly by direct stimulation of sympathetic receptors.

Bloomer et al. (2011b) administered caffeine, DMAA, or combinations of both to volunteers prior to them running 10 km. Six males and 6 females with an average age of 22 years were given 0, 4 mg caffeine/kg, 1 mg DMAA/kg, or a combination of 4 mg caffeine/kg and 1 mg DMAA/kg, in 500 ml water. Treatments were ingested one hour prior to running 10 km on an outdoor track. Each subject completed four test runs with a different treatment before each run, with one week in between each test. Air temperatures during each test ranged from 44°F to 68°F. There were no statistically significant differences between groups in required run time, perceived exertion, self-reporting of mood and vigor, and heart rate during the run. At 5 and 30 minutes post-exercise, the heart rate in the caffeine+DMAA group was higher than the caffeine or DMAA groups, but not the placebo group. Systolic blood pressure in the caffeine+DMAA group at 5 and 30 minutes post-exercise (126 mm Hg) was similar to placebo (126 mm Hg), but lower than the caffeine-alone (141 mm Hg) or DMAA-alone (147 mm Hg) groups. Diastolic blood pressure at 5 minutes post-exercise was similar across groups (64-66 mm Hg), but lower in the DMAA+caffeine group (61 mm Hg). The rate pressure product was similar in the placebo and DMAA+caffeine groups at 5 and 30 minutes post-exercise, but higher in the caffeine-alone or DMAA-alone groups. These data indicate that a combination of 1 mg DMAA/kg and 4 mg caffeine/kg, a dose level approximately equivalent to the maximum product label dose, did not

significantly change physical performance, level of exertion, subject mood or vigor, heart rate, or blood pressure endpoints, compared to placebo, following a very strenuous physical activity.

McCarthy et al. (2012a) examined the effect of single doses of OxyElite Pro™ on hemodynamics of healthy adults for up to two hours after treatment. Six males and 6 females were administered two capsules of OxyElite Pro™ (0.5-0.6 mg DMAA/kg and 2.5-3.2 mg caffeine/kg) or placebo on two separate days in a cross-over study design. An increase in heart rate of 8-11 beats/min (BPM) was reported in the treated group beginning at 60 minutes. Systolic blood pressure increased (112-118 mm Hg) in the treated groups, compared to placebo (101-104 mm Hg) beginning at 30 minutes after dosing. The rate pressure product increased in the treated group at 60 minutes after dosing. There was no increase in diastolic pressure.

Farney et al. (2012) investigated hemodynamic, hematological, and clinical chemistry effects of Jack3d™ after single and 14-day dosing. Seven healthy adult males consumed two scoops (11 g) of Jack3d™ in water for 14 days, resulting in DMAA and caffeine doses of 0.5 and 3 mg/kg/day, respectively. After dosing on days 1 and 14 (acute-phase observations), systolic blood pressure increased (122-123 mm Hg) over pre-ingestion values (109 mm Hg) beginning at 30 minutes. There were no significant differences in acute changes in heart rate, diastolic pressure, or rate pressure product on days 1 or 14. After 14 days of dosing, no significant changes in hemodynamic endpoints compared to day 1 were reported. Further, 14 days of dosing did not affect results of blood tests, including complete blood counts and lipid and metabolic panels.

Farney et al. (2012) also investigated hemodynamic, hematological, and clinical chemistry effects of OxyElite Pro™ after single and 14-day dosing. Four healthy adult males and two females consumed two capsules of OxyElite Pro™ for 14 days, providing DMAA and caffeine doses of 0.6 and 3 mg/kg, respectively. After dosing on days 1 (acute-phase observations), systolic blood pressure increased (116-119 mm Hg) over pre-ingestion values (103 mm Hg) beginning at 60 minutes. There were no significant differences in acute changes in systolic pressure on day 14, or in heart rate, diastolic pressure, or rate pressure product on days 1 or 14. After 14 days of dosing, no significant changes in hemodynamic endpoints compared to day 1 were reported. Further, 14 days of dosing did not affect results of blood tests, including complete blood counts and lipid and metabolic panels.

McCarthy et al. (2012b) examined the effect of an 8-week exposure of OxyElite Pro™ on hemodynamic, hematological, and clinical chemistry endpoints. Groups of 16 healthy, adult males and females consumed 1-2 capsules OxyElite Pro™ or two placebo capsules daily for 8 weeks, resulting in daily DMAA and caffeine doses of 0.3-0.5 and 1.3-2.6 mg/kg, respectively. In the treated group, resting heart rate was slightly, but statistically significantly, higher (69.4 BPM) at the end of the study compared to the beginning (63.3 BPM), but were not different from the placebo control values (65-67 BPM). There were no differences between treatment groups or

pre- or post-study values for systolic or diastolic blood pressure. There were no clinically-relevant differences between treatment groups or across time in hematology, lipid, or metabolic panel endpoints.

Whitehead et al. (2012) examined the effect of a 10-week exposure of Jack3d™ on hemodynamic, hematological, and clinical chemistry endpoints. Groups of 12 or 13 healthy, adult males consumed 1-3 scoops (5.5-16.5 g) of Jack3d™ or placebo powder in water prior to exercise on an average of 4 days/week for 10 weeks. This treatment regimen resulted in DMAA and caffeine exposure ranges of 0.3-0.8 and 1.6-4.9 mg/kg and exercise days. Ten weeks of Jack3d™ use resulted in reported heart rate and systolic and diastolic blood pressure values similar to placebo controls. There were no clinically-relevant differences between treatment groups or across time in hematology, lipid, or metabolic panel endpoints.

There are two additional studies currently being conducted by Bloomer et al. The clinical phase of a pharmacokinetic study to profile DMAA concentration in the blood of 8 male adults consuming 50 mg of DMAA in capsules has been completed. The study investigators also measured heart rate, blood pressure, and body temperature over a 12-hour period post-dosing and again at 24 hours. A 12-week placebo-controlled dietary intervention study is being performed in which groups of 15 adult men will consume placebo, 50 mg DMAA, 250 mg caffeine, or 50 mg DMAA + 250 mg caffeine daily in capsules. Endpoints to be measured at 0, 6, and 12 weeks include hemodynamic parameters, clinical chemistry, hematology, urinalysis, blood markers for oxidative stress, inflammation, and cardiac muscle damage, and electrocardiography. Every two weeks, participants will also self-report endpoints including mild, moderate, or severe changes noticed in heart rate, sleep quality, mental focus, and physical performance. This study is currently scheduled to be completed in 2012.

The clinical studies for DMAA, Jack3d™, and OxyElite Pro™ contain similar findings for the effect of DMAA administered orally with or without caffeine: a transient increase in systolic blood pressure of approximately 12-18% occurs approximately 60-90 minutes after ingestion (Table 1). This is expected, given the sympathomimetic nature of DMAA. Extended exposure exposures of 2 to 10 weeks, either daily or on workout days only, did not result in exposure duration-related increases in resting heart rate or blood pressure. A 12-18% increase in systolic pressure, 10-15% increase in diastolic pressure (in one study, Bloomer et al. 2011a), and 6% increase in heart rate (as seen in one study, McCarthy et al. 2012) in healthy adults for periods of 1-2 hours per day does not constitute an adverse health effect and would not be expected to have long-term adverse consequences on cardiac health. This is particularly true if Jack3d™ or OxyElite Pro™ is used just prior to workouts, as strenuous exercise results in a transient increase in systolic pressure. In fact, no increase in blood pressure was reported after a 10 km run by runners who consumed DMAA+caffeine beforehand (Bloomer et al. 2011b). The similarity for hemodynamic results for DMAA alone or as a component in Jack3d™ or OxyElite Pro™

indicate that the other product components (i.e., amino acid forms, creatinine, and plant extracts) did not influence these endpoints.

The results of the hematological, metabolic, and lipid panel tests in the 2- to 10-week studies indicate that Jack3d™ and OxyElite Pro™ use over an extended period of time does not adversely impact liver or kidney function, as indicated by clinically normal plasma levels of bilirubin, alkaline phosphatase, and aspartate and alanine transaminases, and gamma glutamyl transferase (liver), as well as glucose, blood urea nitrogen (BUN), creatinine, sodium, potassium, and albumin (kidney). Self-reporting of no incidents of discomfort or elevated body temperature during an extended strenuous physical activity (10 km run) or after 10 weeks of episodic workouts indicate that labeled uses of OxyElite Pro™ or Jack3d™ does not increase the susceptibility to induction of hyperthermia or syncope in healthy adults.

Analysis of Association of Adverse Heat-Related Health Effects with Consumption of Jack3d™ and OxyElite Pro™

DMAA-containing supplements such as Jack3d™ and OxyElite Pro™ may be used during extreme heat conditions, which can be associated with effects such as loss of consciousness, hyperthermia, muscle breakdown during exertion, and rapid heartbeat, and kidney and liver failure. An important issue to resolve is whether exposure to dietary supplements containing DMAA and caffeine imparts significant additional risk of causing these or other effects under conditions of extreme heat and physical exertion. The clinical data for DMAA + caffeine, Jack3d™, and OxyElite Pro™ indicate that clinical precursors leading to each of the adverse effects of concern have not been observed, as shown in the following discussion.

Loss of consciousness (syncope): None of the subjects ingesting DMAA at Jack3d™ or OxyElite Pro™ labeled doses reported light-headedness or loss of consciousness during or after a 10 km run (Bloomer et al. 2011b) or while using either product for up to 10 weeks in conjunction with a frequent exercise workout regimen (Farney et al. 2012; McCarthy et al. 2012b; Whitehead et al. 2012). Hemodynamic data from all 6 clinical studies of DMAA never indicate conditions of blood pressure drop that could be associated with diminution of conscious faculties.

Heat injury (hyperthermia): A chemically-induced increase in risk of exertional hyperthermia requires interference with the ability of the body to shed excess heat. This interference may be caused by dehydration, significant decrease in electrolyte concentrations, and/or inhibition of sweat gland function leading to loss of evaporative cooling at the skin surface (Armstrong et al. 2007a). Human studies have shown that caffeine ingestion of less than 600 mg/day in adults does not result in increased diuresis (fluid loss to urine) (Armstrong et al. 2005, 2007b). No data were available to demonstrate the effect of DMAA or other aliphatic amines on diuresis, but epinephrine and norepinephrine (more potent sympathomimetics than DMAA) do not increase diuresis (Billewicz-Stankiewicz et al. 1980). Healthy adults administered single exposures of

DMAA+caffeine or Oxy Elite Pro either resting (Bloomer et al. 2011a; McCarthy et al. 2012 a, 2012b) or prior to running 10 km (Bloomer et al. 2011b) did not report in increase in subjective indicators of thirst, uncharacteristically perfuse sweating, or urinary urge. In a study of healthy adults using DMAA prior to running 10 km in ambient air temperatures ranging from 44°F to 68°F, there was no indication from study subjects of thermal discomfort or change in required exertion level, compared to an identical run performed by the same subjects after consuming a placebo (Bloomer et al. 2011b). These findings from subjects performing very strenuous physical exercise at relatively mild ambient temperatures are useful in that significant changes to body heat regulation would be detected and reported without confounding by high ambient air temperatures. Similarly, subjects using Jack3d™ or OxyElite Pro™ at labeled doses prior to exercise workout for 2 to 10 weeks did not report thermal discomfort (Farney et al. 2012; McCarthy et al. 2012b; Whitehead et al. 2012). Blood clinical chemistry results from the same subjects did not indicate any effect on electrolyte concentrations that could be magnified if exercising in conditions of extreme heat. Thus, clinical data indicate that labeled use of Jack3d™ or OxyElite Pro™ would not increase the risk of heat injury for a healthy adult performing strenuous physical activity in hot conditions.

Exertion-induced muscle breakdown (rhabdomyolysis): Clinical manifestation of exertional rhabdomyolysis may include muscle pain, swelling, and weakness, electrolyte imbalance, decreased renal function, abnormal heart rate, confusion, and gastrointestinal distress. None of these signs, symptoms, or indications from clinical chemistry results from users of labeled doses of Jack3d™ or OxyElite Pro™ were reported in the six clinical studies of DMAA. Thus, use of Jack3d™ or OxyElite Pro™ at labeled doses is unlikely to increase the risk for developing acute or chronic exertional rhabdomyolysis in healthy adults.

Rapid heartbeat (tachycardia): Heart rate data from the six clinical studies of DMAA do not indicate the occurrence of rapid heartbeat/tachycardia, even in subjects using DMAA and caffeine prior to a 10 km run.

Liver failure: Blood samples subjected to metabolic panel examinations were reported for subjects using Jack3d™ or OxyElite Pro™ for 2 to 10 weeks (McCarthy et al, 2012b; Farney et al. 2012; Whitehead et al. 2012). Indications of liver health included blood levels of bilirubin, alkaline phosphatase, aspartate and alanine transaminases, and gamma glutamyl transferase. In all of the multi-dose studies, these parameters were all well within clinical reference ranges, indicating the lack of evidence for subclinical precursors to liver injury or failure.

Kidney failure: Blood samples subjected to metabolic panel examinations were reported for subjects using Jack3d™ or OxyElite Pro™ for 2 to 10 weeks (McCarthy et al, 2012b; Farney et al. 2012; Whitehead et al. 2012). Indications of kidney health included blood levels of glucose, blood urea nitrogen (BUN), creatinine, sodium, potassium, and albumin. In all of the multi-dose studies, these parameters were all well within clinical reference ranges. Normal electrolyte and

plasma protein levels provided no indications of onset of metabolic acidosis that could accompany kidney failure. Thus, there was no indication of evidence for subclinical precursors to kidney injury or failure.

The USFDA maintains a database of user- and clinician-reported adverse events occurring simultaneously with use of dietary supplements as a means of public health surveillance in the U.S. (USFDA 2012). The Adverse Event Reporting (AER) database is updated monthly and analyzed by FDA staff to detect evidence for association of adverse events with use of specific supplements. As evidence points to such associations, USFDA issues AER alerts to the public. To date, no AER alerts have been issues for Jack3d™, OxyElite Pro™, or other DMAA-containing dietary supplements.

There are no data available for effects arising from co-exposures of Jack3d™ or OxyElite Pro™ and other dietary supplements. Authors of a case report of cerebral hemorrhage in a 21-year-old male implicated a mixture of abusive bolus doses of DMAA (approximately 600 mg), caffeine (150 mg), and alcohol as possibly causative (Gee et al. 2010). Such co-exposures are explicitly contraindicated on the Jack3d™ and OxyElite Pro™ product labels. Furthermore, the dose of DMAA consumed in this case was ten-times higher than the maximum recommended daily intake from Jack3d™ or OxyElite Pro™.

Conclusions

The use of DMAA in humans has been documented since the 1940s. It is a naturally occurring aliphatic amine that has sympathomimetic properties, was marketed as an FDA-approved OTC nasal decongestant for 30 years, and is used as a stimulant in dietary supplements, such as Jack3d™ and OxyElite Pro™. Over the past two years, six published clinical studies of DMAA, Jack3d™, and OxyElite Pro™ provided data on the hemodynamic, hematological, liver, and renal safety of these products in healthy adults consuming labeled doses for up to 10 weeks (McCarthy et al, 2012a, 2012b; Farney et al. 2012; Bloomer et al. 2011a, 2011b; Whitehead et al. 2012). This same group of investigators is currently performing two additional clinical studies to inform on the pharmacokinetics of DMAA and to add additional clinical observations throughout 12-weeks of DMAA use by larger groups of volunteers than previously tested. The stimulatory hemodynamic effects, including short-term increases in blood pressure, of DMAA in Jack3d™ and OxyElite Pro™ at labeled usage rates are statistically identical to those from the amount of caffeine in 2-3 cups of coffee. The clinical data indicate lack of changes in clinical markers that would be exhibited as precursors or manifestations of clinically adverse outcomes. Thus, there is no scientific evidence that labeled use of these products by healthy adults will compromise individual health or increase susceptibility to heat-related injuries.

References

Armstrong LE, Casa DJ, Millard-Stafford M, et al. (2007a). Exertional heat illness during training and competition. Med Sci Sports Exercise (Special Communications) 556-572.

Armstrong LE, Casa DJ, Maresh CM, et al. (2007b). Caffeine, fluid-electrolyte balance, temperature regulation, and exercise heat tolerance. Exerc Sports Sci Rev. 35:135-140

Armstrong LE, Pumerantz AC, Roti MW, et al. (2005). Fluid, electrolyte, and renal indices of hydration during 11 days of controlled caffeine consumption. Int J Sport Nutr Exerc Metab. 15:252-265.

Billewicz-Stankiewicz J, Gołabek W, Zaczkiewicz A. (1980). Adrenaline and noradrenaline effects on diuresis. Acta Physiol Pol. 31:305-315.

Bloomer RJ, Harvey IC, Farney TM, et al. (2011a). Effects of dimethylamine and caffeine alone or in combination on heart rate and blood pressure in healthy men and women. The Physician and Sports Med. 39: 111-120.

Bloomer RJ, McCarthy GC, Farney TM, et al. (2011b). Effect of caffeine and 1,3-dimethylamylamine on exercise performance and blood markers of lipolysis and oxidative stress in trained men and women. J. Caffeine Res. 1: 1-9.

Cantox (2011a). Safety review of Jack3d. Prepared for USPlabs LLC. Draft for Discussion. June 2, 2011.

Cantox (2011b). Safety review of Oxy Elite Pro. Prepared for USPlabs LLC. Draft for Discussion. June 8, 2011.

Farney TM, McCarthy CG, Canale RE, et al. (2012). Hemodynamic and hematologic profile of healthy adults ingesting dietary supplements containing 1,3-dimethylamylamine and caffeine. Nutr Metab Insights. 5: 1-12.

Gee P, Jackson S, Easton J. (2010). Another bitter pill: a case of toxicity from DMAA party pills. New Zeal Med J. 123: 124-127.

Li J, Chen M, Li ZC. (2012). Identification and quantification of dimethylamylamine in geranium by liquid chromatography tandem mass spectrometry. (Pre-publication).

Lisi A, Hasick N, Kazlauskas R, et al. (2011). Studies of methyl hexaneamine in supplements and geranium oil. Drug Test Anal. 3:873-6

Marsh DF, Howard A, Herring DA. (1951). The comparative pharmacology of the isomeric nitrogen methyl substituted heptylamines. J Pharmacol Exp Therapeut. 103: 325-329.

McCarthy CG, Farney TM, Canale RE, et al. (2012a). A finished dietary supplement stimulates lipolysis and metabolic rate in young men and women. Nutr Metab Insights. 5: 23-31.

McCarthy CG, Canale RE, Alleman RJ, et al. (2012a). Biochemical and anthropometric effects of a weight loss dietary supplement in healthy men and women. Nutr Metab Insights. 5: 13-22.

Miya TS and Edwards LD. (1953). A pharmacological study of certain alkoxyalkylamines. J Am Pharm Assoc. 42: 107-110.

Nurminen ML, Nittynen L, Korpela R, et al. (1999). Coffee, caffeine and blood pressure: a critical review. Eur J Clin Nutr. 53:831-839.

Ping Z, Jun Q, Qing L. (1992). A study on the chemical constituents of geranium oil. J Guizhou Inst Technol. 25: 82-85.

Robertson D, Frolich JC, Carr RK, et al. (1978). Effects of caffeine on plasma renin activity, catecholamines and blood pressure. N Engl J Med. 298:181-186.

Rohrman E and Shonle HA. (1927). Aminoalkanes as pressor substances. J Am Chem Soc. 66: 1516-1520.

Swanson EE and Chen KK. (1946). Comparison of pressor action in aliphatic amines. J Pharmacol Exp Therapeut. 88: 10-13.

USFDA. (2012). Dietary supplement adverse event reporting alerts. Available online at http://www.fda.gov/food/dietarysupplements/alerts/ucm111110.htm

U.S. Patent Office. (1944). Aminoalkanes. Patent No. 2,350,318. Submitted by Shonle HA and Rohrman E, assignors to Eli Lilly and Company. Patented May, 1044.

Whitehead, PN, Schilling BK, Farney TM, et al. (2012). Impact of a dietary supplement containing 1,3-dimethylamylamine on blood pressure and bloodborne markers of health: a 10-week intervention study. Nutr Metab Insights. 5: 33-39.

Table 1. Summary of Effects from Six Published Clinical Studies of DMAA, Jack3d™, or OxyElite Pro™

Study	Number of Subjects	Exposure Intensity and Duration	Effects Observed / Reported					
			Heart Rate	Systolic Blood Pressure	Diastolic Blood Pressure	Rate Pressure Product	Hematology	Metabolic Panel
Bloomer et al. (2011a)	5 males 5 females	Single exposure of DMAA (0.6-0.7 or 0.9-1.0 mg/kg) and/or caffeine (2.8-3.4 mg/kg)	NCRC	↑6-18%, decreasing after 90 min	↑10-15%	↑9%	NT	NT
Bloomer et al. (2011b)	6 males 6 females	Single exposure of placebo, DMAA (1 mg/kg), caffeine (4 mg/kg), or both	NCRC	↑17%, decreasing to baseline after 30 min post-exercise	NCRC	NCRC	NT	NT
McCarthy et al (2012a)	6 males 6 females	Single exposure (2 capsules) Of Oxy Elite Pro (0.5-0.6 mg DMAA/kg And 2.5-3.2 mg caffeine/kg)	↑ 6% thru 2 hrs	↑15% thru 2 hrs	NCRC	↑22%	NT	NT
Farney et al. (2012a)	7 males	Single exposure (2 scoops) of Jack3d (0.5 mg DMAA/kg and 3 mg caffeine/kg)	NCRC	↑12%, decreasing after 60 min	NCRC	NCRC	NT	NT
Farney et al. (2012a)	4 males 2 females	Single exposure (2 capsules) of Oxy Elite Pro (0.6 mg DMAA/kg and 3 mg caffeine/kg)	NCRC	↑16%, decreasing after 90 min	NCRC	NCRC	NT	NT
Farney et al. (2012a)	7 males	14-day exposure (2 scoops/day) of Jack3d (0.5 mg DMAA/kg and 3 mg caffeine/kg)	NCRC	↑13%, decreasing after 90 min	NCRC	NCRC	NCRC	NCRC
Farney et al. (2012a)	4 males 2 females	14-day exposure (2 capsules/day) of Jack3d (0.6 mg DMAA/kg and 3 mg caffeine/kg)	NCRC	↑14%, decreasing after 60 min	NCRC	NCRC	NCRC	NCRC
McCarthy et al (2012b)	16 males 16 females	8-week exposure (2 capsules/day) of placebo or Oxy Elite Pro (0.3-0.5 mg DMAA/kg and 1.3-2.6 mg caffeine/kg)	NCRC	NCRC	NCRC	NCRC	NCRC	NCRC
Whitehead et al. (2012)	30 males	10-week exposure (2.4 scoops/day) of placebo or Jack3d (0.3-0.8 mg DMAA/kg and 1.6-4.9 mg caffeine/kg)	NCRC	NCRC	NCRC	NCRC	NCRC	NCRC

NCRC = No clinically-relevant changes; NT = Not Tested